

IN THE UNITED STATES PATENT AND
TRADEMARK OFFICE*21/D*
CD
PATENT*7/10/02*

Applicant(s): John F. Stone

Docket No.: 36435.0100

Serial No.: 09/498,135

Priority Date: February 4, 2000

Title: CHROMOSOME-BASED METHOD FOR
FACILITATING DISEASE DIAGNOSISExaminer: Goldberg
Group Art 1655
Unit:AMENDMENT

Commissioner for Patents
Box RCE
Washington, D.C. 20231

Dear Sir:

Applicant hereby responds to the Office Action dated January 8, 2002, for which the period to respond is extended by three months to July 8, 2002. Applicant respectfully requests reconsideration and allowance of all pending claims.

IN THE CLAIMS

Please cancel claims 8, 9 without prejudice or disclaimer and amend claims 1, 11, and 16 as follows.

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1. (4x Amended) A method suitable for facilitating disease diagnosis, the method comprising the steps of:

exposing cells of a patient, suspected of having a disease for which chromosome damage is diagnostic, to a chromosome damaging agent selected to damage chromosomes within the nuclei of the cells to produce chromosome fragments having broken ends;

marking at least some of the broken ends, wherein said marking step includes adding dNTP to at least a portion of the broken ends and exposing the broken ends to fluoresceinated material; and

D1 analyzing the marked broken ends within interphase cell nuclei to determine whether the cells were affected by the disease, wherein said analyzing includes comparing information obtained from cells of a patient suspected of having a disease to information obtained from cells of suspected healthy patients.

11. (4x Amended) A method for analyzing an effect of disease on cells, the method comprising the steps of:

D2 preparing cells suspected of being affected by a disease for which chromosome damage is diagnostic by exposing the cells to a chromosome breakage agent to form chromosome pieces having ends within nuclei of the cells;

marking at least a portion of the ends within interphase nuclei with dNTP;
counting a number of marked ends to analyze the effect of the disease on cells;

and

comparing said number of marked ends to information obtained from a control group.

16. (4x Amended) A method suitable for facilitating diagnosis of Alzheimer's disease, the method comprising the steps of:

D3 exposing cells thought to be affected by Alzheimer's disease to a chromosome damaging agent;

exposing the cells thought to be affected by Alzheimer's disease to a chromosome breakage agent to form chromosome pieces having ends;

marking at least some of the ends within interphase nuclei with dNTP;
measuring an amount of marked chromosome ends; and
comparing a number of marked chromosome ends present in the cells thought to be affected by Alzheimer's disease to information relating to a control group.

REMARKS

The undersigned thanks Examiner Fredman and Examiner Goldberg for the courtesies extended in a June 13, 2002 telephone conference. During the telephone conference, we discussed submission of affidavits to overcome the alleged *prima facie* case of obviousness and how such would overcome rejections to pending claim 9. The affidavits are being submitted under a separate cover. In an effort to further prosecution of the present case, Applicant herewith has amended independent claims 1, 11, and 16 to incorporate the limitation of claim 9, while hereby expressly reserving the right to pursue broader subject matter in other, related applications. In view of the amendments set forth herein, Applicant submits that all pending claims are allowable over the cited references and therefore earnestly requests allowance of all pending claims.

35 U.S.C. § 103 Rejections

Claims 1-4, 6-8, 11, 13, and 15-17 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over Cherry et al. in view of Marcon et al. Applicant traverses this rejection.

Claims 1, 11, and 16, from which claims 2-4, 6-8, 15 and 17 depend, have been amended to include the limitation "adding dNTP" in claim 1 and "with dNTP" in claims 11 and 16, which is the limitation previously set forth in claim 9. Nowhere do either of Cherry et al. or Marcon et al. teach or suggest use of "dNTP." Accordingly, Applicant requests that the Examiner reconsider and withdraw this rejection to claims 1-4, 6-8, 11, 13, and 15-17.

Claims 1-2, 4, 11, 13, and 16-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. in view of Marcon et al. Again, Applicant traverses this rejection. As noted above, independent claims 1, 11, and 16 have been amended to include the limitation "dNTP." Nowhere does Chen et al. or Marcon et al. teach or suggest the use of "dTNP" in connection with the claimed invention. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection to claims 1-2, 4, 11, 13, and 16-17.

Claims 1-6 and 11-13, and 15-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Parshad et al. in view of Marcon et al. Applicant traverses this rejection. Neither Parshad et al. nor Marcon et al. teach or suggest use of "dTNP." Accordingly, Applicant

requests that the Examiner reconsider and withdraw this rejection to claims 1-6 and 11-13, and 15-17.

Finally, claims 8-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cherry et al. in view of in view of Marcon et al., and in further view of Gorczyca et al. Applicant traverses this rejection with respect to claim 10 because none of Cherry et al., Marcon et al., Gorczyca et al., or a combination thereof, teach or suggest the claimed invention and submits that the rejection is moot with respect to cancelled claims 8 and 9.

Specifically, no combination of the references teaches or suggests "a method suitable for facilitating disease diagnosis" including "marking at least some of the broken ends, wherein said marking step includes adding dNTP to at least a portion of the broken ends and exposing the broken ends to fluoresceinated material" and "analyzing the marked broken ends within interphase cell nuclei" as set forth in claim 1, from which claim 10 depends.

In view of the foregoing arguments, Applicant submits that all pending claims are allowable over the cited references. Applicant therefore earnestly solicits allowance of pending claims 1-7, 10-13, and 15-17. The undersigned would welcome a telephone call at the telephone number listed below if such would advance prosecution of this application.

Respectfully submitted,

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